APR - 8 2010

Chapter III 510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: K100046

Sponsor **Manufacturer**	**Guangdong Biolight Meditech Co., Ltd** Innovation First Road, Technology Innovation Coast Zhuhai, Guangdong, 519085, China **Contact Person:** Mr. Tianbao Li, Chief Engineer **Tel:** +86-756-3399963 **Fax:** +86-756-3399989 **E-mail:** li_tb@blt.com.cn
Submission Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No.19, Lane 999, Zhongshan Road (S-2) Shanghai, 200030, China
Proposed Device	
Trade Name	M Seires Patient Monitor
Model	M66 M69 M7000 M8000 M9000
Classification Name	Monitor, Physiological, Patient
Product Code	MHX
Regulation Number	21 CFR 870.1025
Panel	Cardiovascular
Subsequent Product Code	DRT, DXN, DSK, DQA, BZQ, CCK, FLL
Device Description	The proposed device, M Series Patient Monitor (M66, M69, M8000 and M9000) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient. It has the alarming function with audio and visual alarming, which may raise the user attention of system error and exceeding the pre-set limit of

	physiological parameter, and data storage function, which can replay the data and alarming event. The device is driven by AC or DC power supply.
Intended Use	M Series Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient. The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance.
Testing Summary	Laboratory testing was conducted to validate and verify that M Series Patient Monitor met all design specifications, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of all consensus standards
Predicate Device	PM-7000 Patient Monitor (K072346)
SE Determination	The proposed device, M Series Patient Monitor, is Substantially Equivalent (SE) to the predicate device, PM-7000 Patient Monitor (K072346).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 8 2010

Guangdong Biolight Meditech Co., Ltd.
c/o Diana Hong
Suite 5D, NO.19, Lane 999 Zhongshan Road (S-2)
Shanghai, China, 200030

Re: K100046
Trade/Device Name: M Series Patient Monitor (M66, M69, M7000, M8000 and M9000 models).
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor
Regulatory Class: Class II (two)
Product Code: MHX, DRT, DXN, DSK, DQA, BZQ, CCK, FFL
Dated: March 19, 2010
Received: March 22, 2010

Dear Ms Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

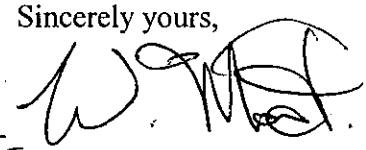
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100046

Exhibit #A Indication for Use Form

510(k) Number: K100046

Device Name: M Series Patient Monitor

Indications for Use:

M Series Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of adult, pediatric and neonatal patient as listed below:

Parameters	M66	M69	M7000	M8000	M9000
ECG	x	x	x	x	x
Heart Rate	x	x	x	x	x
Respiration Rate (RESP)	x	x	x	x	x
Pulse Oxygen Saturation (SpO2)	x	x	x	x	x
Non-Invasive Blood Pressure (NIBP)	x	x	x	x	x
Invasive Blood Pressure (IBP)	x	x	--	x	x
Carbon Dioxide (CO2)	x	x	--	x	x
Temperature (TEMP)	x	x	x	x	x

The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

It is not intended for helicopter transport or hospital ambulance

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100046